Allegiance
a Cardinal Health company

K011078

JUL 13 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
Malleable Shaft Clamp

Manufacturer:	Allegiance Healthcare Corporation V. Mueller Business Unit 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact	Lance Marconi 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3312
Date Summary Prepared:	April 6, 2000
Product Trade Name:	Malleable Shaft Clamp
Common Name:	Vascular Clamp
Classification:	Vascular Clamp
Predicate Device: (K974769)	Cosgrove Vascular Clamp
Description:	The Allegiance Malleable Shaft Clamp consists of reusable stainless steel handle and jaws, featuring a disposable flexible shaft which is supplied sterile. This clamp is designed to be used with a variety of inserts, which gently surround blood vessels and offer differing degrees of atraumatic occlusion. Following the clamping of the blood vessel, the shaft of the device can be bent out of the way to enhance visualization of and access to the operative field.

Intended Use:	The Allegiance Malleable Shaft Clamp is intended to be used for the temporary occlusion of blood vessels and other delicate vessels during surgery. Surgical applications include pulmonary and gastrointestinal procedures, peripheral clamping, minimally invasive and standard open cardiovascular and cardio-thoracic procedures such as occlusion of the aorta and vena cava, cross clamping of the aorta, etc.
Substantial Equivalence:	The Allegiance Malleable Shaft Clamp is substantially equivalent to the Allegiance Cosgrove Vascular Clamp, in that: • Intended use is the same • Performance attributes are the same • Atraumatic Jaw design characteristic is the same • Materials for handle and jaws are the same
Summary of Testing:	All materials used in the fabrication of the Malleable Shaft Clamp were subjected to performance testing, physical testing, and biological clearance for use testing to evaluate the safety, effectiveness and reliability of the device. All test results were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2001

Allegiance Healthcare Corporation
c/o Mr. Joseph A. Mertis
Director, Regulatory Affairs
1500 Waukegan Road, Building WM
McGaw Park, Illinois 60085

Re: K011078
Trade/Device Name: Malleable Shaft Clamp
Regulation Number: 870.4450
Regulatory Class: II (two)
Product Code: DXC
Dated: July 10, 2001
Received: July 10, 2001

Dear Mr. Mertis:

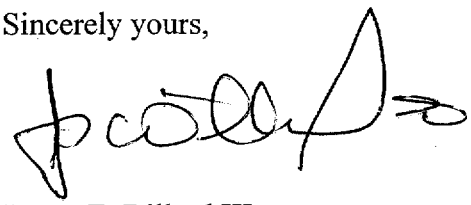
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Allegiance
a Cardinal Health company

Allegiance Healthcare Corporation
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McGaw Park, Illinois 60085 USA
847-578-3636 FAX: 847-785-2461

Special 510(k) Device Modification: Malleable Shaft Clamp
V. Mueller Business Unit

510(k) Number (if known): Unknown

Device Name: Malleable Shaft Clamp

Indications For Use: Used to occlude a blood vessel temporarily. Used in pulmonary and gastrointestinal, procedures, and can be used to clamp over indwelling catheters. Also used in minimally invasive and standard open cardiovascular procedures for temporary occlusion of a blood vessel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011078

Prescription Use ✓ or **Over-The Counter Use** _____
(Per 21 CFR 801.109)